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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,977	02/16/2001	Seiya Takahashi	14328	3787

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EXAMINER	
GORDON, BRIAN R	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/784,977	TAKAHASHI ET AL.	
	Examiner	Art Unit	
	Brian R. Gordon	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,14 and 28-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4, 14, 28-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 21, 2004 has been entered.

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Interpretations

2. It appears as if applicant has amended the claim to recite similar limitations of the original claim 1. The original claim 1 (applicable to 58 and 59, also) required the holding member to be moved by the driving means. The instant claims no longer recite such a limitation. The amended claim now implies the actuator moves while the conduit (liquid holding member) is not required to move in order to dispense the liquid.

Claims 1, 58, and 59 differ only in the content of the preamble. The recitation that the device is a micro array manufacturing apparatus is has not been given

patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. *Kropa v. Robie*, 88 USPQ 478 (CCPA1951). The claims are essentially the same and are considered to be redundant claims. Redundant claims should be canceled.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 28-40, 42-43, 48, 50, 53, 55 57-58 and 62-63 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 57 it is unclear how a single conduit member comprises a plurality of conduit members.

5. Claim 58 recites the limitation "the conduit member" in the next to last line. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 53 recites the limitation "the liquid container" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 48 recites the limitation "the air space" in line 2. There is insufficient antecedent basis for this limitation in the claim.

8. Claims 28-40, 42-43, 48, 50, 53, 55, and 62-63 are directed to process limitations of how the device is used or intended use of the device. The claims do not further limit

the structure of the device. The claims moreso address a particular use of the device or the process of how the device is used to dispense a liquid and what occurs during that process.

The functional recitations directed to when a certain action takes place (such as for example, dispensing in claims 29, movement in claim 32 and others) have not been given patentable weight because it is in narrative form. In order to be given patentable weight, a functional recitation must be expressed as a "means" for performing the specified function, as set forth in 35 USC 112, 6th paragraph, and must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language. *In re Fuller*, 1929 C.D. 172; 388 O.F.279.

It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

It has been held that the recitation that an element is "adapted to" or "capable of" perfoming a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Response to Arguments

Applicant's arguments filed July 21, 2004 have been fully considered but they are not persuasive. As recited above the only structure limitations required in the claims (1 and 58-61) are liquid holding means and an actuator the moves or moves the liquid holding member. The examiner asserts actuators of the prior art are capable of moving in vertical directions thereby being capable of functioning as claimed by applicant.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1, 28-40, 42-53, 55, 57-66 are rejected under 35 U.S.C. 102(e) as being anticipated by Feygin US 5,957,167.

Feygin discloses a method that is carried out using a micro volume liquid dispenser that includes, as a liquid carrier, a plurality of fluid-dispensing members. Each fluid-dispensing member comprises two opposed surfaces in spaced relation to one another and suitably configured for aspiring and holding (liquid holding member/conduit) a small volume of liquid via capillary action. Each fluid-dispensing member retains and delivers a liquid volume within the range of about 0.5 to about 5 microliters. The present micro volume liquid dispenser further includes an actuator (driving member/actuator) for moving/accelerating the fluid-dispensing members and for stopping/abruptly decelerating the fluid-dispensing members. The actuator can use a biasing member, such as a spring, for accelerating the fluid-dispensing members, and a "stop" for abruptly decelerating the fluid-dispensing members. Alternatively, the actuator can utilize more sophisticated pneumatic, hydraulic or electrodynamic systems. As noted above, abruptly decelerating moving fluid-dispensing members causes retained liquid to issue therefrom. Such dispensed liquid can be directed toward, and received by, an intended receiver.

As seen in the figures the end of the holding member tapers in a direction toward the deposition substrate.

11. Claims 1, 4, are 57-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Shalon et al. US 6,309,891.

Shalon et al. disclose a printing system comprising a pod, a **detachable** printing device, a substrate, a positioner and a preservation device, wherein (a) the pod comprises a receptacle for reversibly attaching an attachment portion of the printing device; (b) the printing device comprises a reservoir containing a liquid comprising a predetermined agent and in fluid connection with the reservoir, a capillary comprising an axial bore having proximal and distal openings to ambient pressure and a printing tip comprising the distal opening and which prints the agent on the substrate; (c) the positioner moves (actuator) the pod relative to the substrate; and (d) the preservation device is within, containing or in contact with the printing device and preserves the capability of the printing device to print the agent on the substrate over long-term storage.

Suitable printing devices include any structural member which combines by fluid connection the requisite reservoir and capillary (liquid holding member/conduit). For example, the printing device may simply be a capillary comprising a liquid-filled bore having a proximate reservoir portion and terminating at a distal portion comprising the printing tip. Alternatively, the reservoir may comprise a more voluminous non-capillary liquid filled chamber having a relatively larger internal diameter in fluid connection with a

capillary comprising the printing tip. The reservoir portion of the printing device is adapted to contain and contains a liquid comprising a predetermined agent.

Suitable positioners include any device which provides the requisite positioning of the printing device to effect the desired printing sites on the substrate. Frequently, the positioner will provide a first positioning within the two-dimensional plane of the substrate surface and a second positioning perpendicular to the surface to effect contact printing on the surface. The positioner is generally electomechanically operated by a computer controlled robot.

The invention provides methods of making, using and storing the subject systems including methods for printing liquids comprising agents or analytes on substrates with the printing systems, particularly printing methods which comprise the step of decelerating the capillary to move the liquid through the bore, out the tip and onto the substrate (dispensing movment). A wide variety of methods may be used for loading and/or unloading the printing devices, including passive capillary loading and unloading from the printing tip, vacuum-assisted unloading, active pressure purging, etc.

Referring to FIG. 20, a printing device 11 is shown in fluid connection through tubing 181 with a sample reservoir 201.

Again, it is noted that claims 28-40, 42-43, 48, 50, 53, 55, and 62-63 are in the form of method steps and do not further limit the structure of the claims that they depend upon. The claims are directed to process steps in which the device is used in a particular manner, which are not accorded patentable weight in claims directed to the apparatus.

12. Claim 1, 14, 28-50, 54-66 are rejected under 35 U.S.C. 102(e) as being anticipated by Rose et al. US 6,551,557.

Rose et al. disclose a ceramic tip and a random access print head for the transfer of microfluidic quantities of fluid. The print head can randomly collect and deposit fluid samples to transfer the samples from a source plate to a target. The print head can also be programmed to create a direct map of the fluid samples from the source plate on the target or to create any desired pattern or print on the target. The tip and print head can be used for a wide variety of applications such as DNA microarraying and compound reformatting. In one preferred embodiment, the tip is used as a capillary or "gravity" pin to draw or collect source fluid and "spot" or deposit the fluid onto the target via physical contact (touch-off). In another preferred embodiment, the tip is used in conjunction with an aspirate-dispense system to actively aspirate source fluid and deposit the fluid via a contact or non-contact approach.

The contact transfer tip (liquid holding member/ conduit) generally comprises a substantially cylindrical upper body portion, a substantially tapered lower body portion and a lumen cavity. The substantially cylindrical upper body portion has a first outside diameter. The substantially tapered lower body portion has a second outside diameter at a transition portion thereof which is substantially equal to the first outside diameter of the upper portion. The substantially tapered lower body portion further has a third diameter at a lower-most end thereof which is smaller than the first or second diameters and which approximately equals the diameter of a spot or dot of fluid desired to be deposited onto the target substrate.

In use, initially all the tips 200 (FIG. 3) are raised by energizing the solenoids 238. The print head 230 is positioned and aligned over the source 29 by utilizing the robot arm 252 and/or the movable platforms 254. For random access collection, a first tip 200 is lowered by de-energizing or turning off the corresponding solenoid 238. The first tip 200 dips into a microwell of the source plate 29 to draw fluid by capillary action. The first tip 200 is raised by energizing the corresponding solenoid 238 (actuator). Relative motion is provided between the source plate 29 and the print head 230, by the robot arm 252 and/or the movable platform 254, to align a second tip 200 with a corresponding microwell of the source plate 29. The second tip 200 is lowered and collects source fluid from the microwell. The second tip 200 is then raised. Subsequent tips 200 are lowered and raised in a similar manner. This random access collection process is continued until all the tips 200 are loaded with the sample fluid.

In one preferred embodiment, a **wash station** (washing means) 256 (FIG. 3) is provided in combination or conjunction with the random access tip array 230 to maintain a dry tip. The wash station 256 generally comprises a vacuum dry system 79 (FIGS. 3 and 6A) to remove any excess fluid that may have adhered to the outer surface of the tip 200 during dipping of the tips 200 in the source reagent or due to any moisture build-up on the outer surface of the tip 200, for example, due to condensation from the air environment.

Referring to FIG. 7, the syringe **pump 22** (may be used to aspirate air) is connected to the reservoir 16 and the dispenser 12 using tubing 23 provided with luer-type fittings for connection to the syringe and dispenser. Various shut-off valves 25 and

check valves (not shown) may also be used, as desired or needed, to direct the flow of fluid 14 to and/or from the reservoir 16, syringe pump 22 and dispenser 12. The reservoir 16 contains a **wash or system fluid 14**, such as distilled water, which fills most of the aspirate-dispense system 10.

In one form of the present invention a solenoid dispenser 12, schematically illustrated in FIG. 11, is preferred. Referring to FIG. 11, the solenoid valve dispenser 12 generally comprises a solenoid-actuated drop-on-demand valve 20, including a valve portion 34 and a solenoid actuator 32, hydraulically coupled to the tube or tip 200 of the present invention. The nozzle 214 of the tip 200 serves as the aspirating and dispensing nozzle. The solenoid valve 20 is energized by one or more electrical pulses 13 provided by a pulse generator 19 to open and close the valve 20 at a predetermined frequency and/or duty cycle. A detailed description of one typical solenoid-actuated valve can be found in U.S. Pat. No. 5,741,554, incorporated herein by reference. The tip (FIGS. 1 and 7) of the present invention may also be used in conjunction with a number of other dispensers well known in the art for dispensing a liquid, such as a **piezoelectric** dispenser (deforms internal shape of the holding member), a fluid impulse dispenser, a heat actuated dispenser (device for adding thermal energy) or the like.

In one preferred embodiment, prior to aspiration of source fluid the syringe pump 22 (FIG. 7) is operated in the reverse direction with the nozzle orifice 216 (FIG. 1) exposed to the atmosphere to draw a small quantity of **air** into the tip 200. Referring to FIG. 13, this forms a small air bubble 262 within the system fluid 14 in the tip 200. The volume of the bubble 262 can be in the range from less than about 0.5 μL to greater

than about 1.0 μL. The tip 200 is then dipped in the source fluid and the syringe pump 22 is decremented to aspirate source fluid 264 (FIG. 13) into the tip 200. In effect, the bubble 262 causes the aspirated fluid laminar velocity profile 266 to have a generally blunt shape by reducing the fluid drag imposed on the aspirated fluid 264 near the tip inner surface or wall 221. Advantageously, this reduces the area of the interface between the system fluid 14 and the aspirated source fluid 264, and hence desirably reduces the mixing and dilution of the aspirated fluid 264 with the system fluid 14.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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